

**REMARKS**

Reconsideration of the allowability of the present application in view of the above amendments and the following remarks is requested respectfully.

Discussion of the Claims

In the present Action, the Examiner acted upon Claims 114, 118-121, 123-135, and 144. In the present Reply, Claims 121, 123, 126-128, and 135 have been amended.

Discussion of the Amendments

Claim 123 has been amended as suggested by the Examiner to recite proper antecedent basis language. Claims 121, 126-128, and 135 have been amended to more particularly recite the claimed invention and to address clerical issues. Support may be found in the application at pages 6-7 (with respect to the PCT publication). No new matter has been added.

Allowable Subject Matter

Applicant acknowledges with appreciation that the Examiner has indicated that Claims 114, 118-120, and 132-134 are in condition for allowance.

Discussion of the Examiner's Claim Objections for Informalities

Applicant notes with appreciation that the Examiner has withdrawn the previous objection to the claims.

In the present Action, the Examiner has objected to Claim 123 for alleged informalities.

To expedite prosecution of the application, Claim 123 has been amended as suggested by the Examiner. Accordingly, Applicant respectfully requests that the Examiner's objection

to Claim 123 be withdrawn.

Discussion of the Examiner's  
Enablement Requirement Rejection Under Section 112, First Paragraph

Claims 121, 123-131, 135, 141, and 144 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. According to the Examiner, the application does not provide an enabling disclosure with respect to delivery of all of the active agents recited in the claims. Applicant traverses respectfully.

The standard by which to judge whether a disclosure is enabling is whether the disclosure enables one skilled in the art to practice the invention without undue experimentation. MPEP §2164.01. The fact that the experimentation may be complex does not render it undue. MPEP §2164.01. Indeed, experimentation may not be considered undue even if a "considerable amount" is required; if, for example, the experimentation is merely routine, or if the specification provides a reasonable amount of guidance. See In re Wands, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988).

As the Examiner has acknowledged at page 3 of the present Action, Applicant's disclosure is enabling for the claimed d-form retro-inverted peptides. The claimed peptides have been demonstrated to enhance the bioavailability of an active agent bound to the peptides. A specific example is provided regarding the enhancement of the bioavailability of insulin, as also noted by the Examiner at page 4 of the Action.

The additional active agents recited in the claims would have been well known to the skilled artisan at the time of filing of the present application, and the conditions that may be treated by any of the claimed active agents would also have been known in the art. Given that the recited active agents were known, in view of the guidance provided by Applicant's disclosure regarding the use of the claimed peptides to increase the bioavailability of active agents bound to the peptides, one skilled in the art would not have to engage in undue experimentation in order to produce a composition comprising the claimed peptide bound to a

material comprising any of the claimed active agents. The use of the claimed compositions to treat a particular disease or disorder might involve some amount of experimentation; however, since the structure of the retro-inverted peptides are provided to the skilled artisan by Applicant's disclosure, and the claimed active agents and their uses are well known to the art, such routine experimentation would not be considered undue.

In view of the foregoing, Applicant submits that the present claims are enabled by the disclosure and requests withdrawal of the rejection.

Discussion of the Examiner's Rejection under Section 112, Second Paragraph

Claims 121, 123-131, 135, 141, and 144 stand rejected under 35 U.S.C. § 112, second paragraph, for allegedly failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicant traverses respectfully.

The Examiner alleges that the claims are indefinite for reciting "a broad set of active agents/drugs, which are intended for treatment of [certain] diseases/disorder[s]". Action at page 6. It is unclear how the alleged breadth of claim scope renders the claims indefinite. Indeed, as noted in MPEP § 2173.04, the breadth of a claim is not to be equated with indefiniteness. (*In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971)) If the scope of the subject matter embraced by the claims is clear, and if Applicant has not otherwise indicated an intention that the invention is to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph. Applicant notes that the Examiner has not pointed out any way in which Applicant has indicated an intention for the invention to encompass a scope different from that defined in the claims.

Applicant submits respectfully that the scope of the referenced claims would be clear to one of skill in the art. With respect to Claim 121, Applicant points out that, while the claim recites a number of diseases/disorders and a number of drugs that may be used to treat the same, the claim is structured such that the skilled artisan would clearly understand the

nature of the claimed composition. As noted, the claim recites a number of diseases and disorders that may be treated by the claimed composition. In the following portion of the claim, certain classes of active agents are recited. In the final portion of the claim, specific active agents are recited. Thus, the recitations of the claim become progressively more specific. One of ordinary skill in the art would possess the understanding to apply the appropriate classes of drugs and specific drugs within those classes to treat one of the recited diseases/disorders. Therefore, Claim 121, as well as the claims that depend from Claim 121, and Claim 135, which is similarly structured, clearly define the claimed composition.

Furthermore, it appears that the rejection for alleged lack of enablement under 35 U.S.C. § 112, first paragraph, may have been inappropriately combined with a rejection for alleged indefiniteness under 35 U.S.C. § 112, second paragraph. However, as noted in MPEP § 2174, the requirements of the first and second paragraphs of 35 U.S.C. 112 are separate and distinct. If, for example, the enabling disclosure of a specification is not considered to be commensurate in scope with the subject matter encompassed by a claim, that alone does not render the claim imprecise or indefinite or otherwise not in compliance with 35 U.S.C. § 112, second paragraph.

In view of the foregoing, Applicant requests withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

#### Conclusion

For the reasons expressed above, Applicant requests that the Examiner reconsider and withdraw the rejections. An early and favorable allowance is requested respectfully.

If the Examiner believes that a telephone conference would expedite prosecution of this application, the undersigned may be contacted at the number indicated below.

A petition for an extension of time for one (1) month, through March 2, 2008, also accompanies this Reply. The Commissioner is hereby authorized to charge any additional

In re Application of Daniel O'Mahony  
Application No. 09/443,986

Atty. Docket No. P26478-A USA  
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fees or credit any overpayment associated with this communication to Deposit Account No.  
19-5425.

Respectfully submitted,

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